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10/574,016	03/29/2006	Yuji Ueno	Q107169	4347

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,016	UENO ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 3/29/06 has been entered.

Claims 1-21 are pending.

2. Applicant's election without traverse of Group II, claims 12-21, drawn to a solution-type antibody preparation is acknowledged.

Accordingly, claims 1-11 are withdrawn from further consideration by the examiner under 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 12-21 drawn to a solution-type antibody preparation are under consideration in the instant application.

3. Applicant's claim for foreign priority under 35. U.S.C. 119 (a)-(d) is acknowledged.

4. Applicant's IDS filed on 3/29/06 is acknowledged.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-19 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "glycine concentration…" in claim 16 does not have antecedent basis in claim 13 and the phrase " the citric acid..." as in claims 17 and 18 does not have antecedent basis in claim 12.

Claim 16 depends on claim 15 which is ultimately being depended upon any one of claims 12-14. As claim 13 does not require glycine, claim 16 should only be depended upon claim 12 or 14.

Given that claim 16 is being depended on claim 13 which does not require glycine, the phrase "glycine concentration…" as in claim 16 has an insufficient antecedent basis for claim 13.

Claims 17-18 depend on claims 15-16 that are ultimately being depended upon any one of claims 12-14. As claim 12 does not require citric acid, claim 16 should only be depended upon claim 13. Given that claim 16 is being depended on claim 12 which does not require citric acid, the phrase " the citric acid..." as in claims 17 and 18 has an insufficient antecedent basis for claim 12.

Moreover, "the pH" as in claim 19 has no antecedent basis in the base claims 12-16 and 18.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 12, 15 and 16 are rejected under 35 U.S.C. 102(a)(e) as being anticipated by U.S. Pub. No. 2003/019316A1 as is evidenced by glycine MSDS (Mallinckroadt Chemicals, 2005, p. 1-6).

The '316 publication teaches that an antibody formulation comprising an antibody and glycine where in the glycine concentration is 0.2M and the antibody concentration is about 2mg/ml (Example 4-5, Fig. 13, claims 1-6). Suppressing formation of soluble association of antibody is an inherent property of glycine.

Given that the referenced formulation does not undergo any process after dialysis (Example 5) to solidify (e.g. lyophilization), it is deemed to remain in solution and the solution type preparation is included.

The '316 publication further teaches that the preparation comprising glycine is more stable because it reduces aggregation ([0089]).

As is evidenced by the glycine MSDS on p. 1, the molecular weight of glycine is 75g, the concentration of 1M (mole/Liter) is calculated as 75mg/ml. Given that the 0.2M of glycine is equivalent to 15mg/ml, claim 16 is included in this rejection. Therefore, the reference teachings anticipate the claimed invention.

9. Claims 13, 15 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/37329 (IDS reference) as is evidenced by the specification on p. 17.

The '329 publication teaches an isotonic formulation comprising a humanized antibody and citrate wherein the antibody concentration is 0.5mg/ml to 10mg/ml, the citrate concentration is 5 to 20mmol/L and the pH of the formulation is 5.5 (claims 1-9). The '329 publication further teaches addition of polysorbate 80 (e.g. non-ionic surfactant, p. 9). "Suppressing formation of a chemically degraded product of said antibody" is an inherent property of citrate (or citric acid)

As is evidenced by the instant specification on p. 17, citric acid includes citrate, the limitation is met. Therefore, the reference teachings anticipate the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 14-20 are rejected under 35 U.S.C. 103 as being unpatentable over WO 99/37329 (IDS reference) in view of U.S. 2003/019316A1.

The ‘329 publication has been discussed, supra.

The ‘329 publication does not teach addition of glycine buffer as in claim 14.

However, the ‘316 publication teaches addition of glycine improves stabilization of preparation as it reduces aggregation ([0089]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycine as taught by the ‘316 publication to the antibody formulation taught by the '329 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the addition of glycine improves the stability of the antibody formulation by reducing aggregation.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/37329 (IDS reference) in view of U.S. 2003/019316A1 as applied to claims 14-20 above, and further in view of U.S. Pat. No. 6,488,930B1.

The ‘329 publication and the ‘316 publication have been discussed, supra.

The ‘329 publication or the '316 publication does not teach a humanized antibody to CCR4 as in claim 21.

However, the ‘930 patent teaches a composition comprising a humanized CCR4 antibody (claims 6 and 47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the stabilizing formation taught by the ‘316 publication and the '329 publication into a CCR4 humanized antibody taught by the ‘930 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the formulation taught by the '316 and the '329 publications improve stability of the antibody formulation.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/37329 (IDS reference) in view of U.S. 2003/019316A1 as applied to claims 14-20 above, and further in view of U.S.Pat. No. 6,437,098B1.

The ‘329 publication and the ‘316 publication have been discussed, supra.

The ‘329 publication or the '316 publication does not teach a humanized antibody to ganglioside GD3 as in claim 21.

However, the ‘098 patent teaches a humanized ganglioside GD3 antibody (claims 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the stabilizing formation taught by the ‘316 publication and the '329 publication into a ganglioside GD3 humanized antibody taught by the ‘098 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the formulation taught by the '316 and the '329 publications improve stability of the antibody formulation.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claims are allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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July 24, 2008

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